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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/715,962      | 11/17/2000  | Klaus Raming         | Mo-5998/LeA-34.074  | 7971             |

157 7590 01/13/2003

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01/13/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                                      |                                      |
|--------------------------------------|--------------------------------------|
| Application No.<br><b>09/715,962</b> | Applicant(s)<br><b>Raming et al.</b> |
| Examiner<br><b>Michael Brannock</b>  | Art Unit<br><b>1646</b>              |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 28, 2002.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 35 and 48-55 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 48 is/are allowed.

6)  Claim(s) 35 and 49-55 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

Art Unit: 1646

## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

1. Applicant is notified that the amendments put forth in Paper 9, 10/28/02, have been entered in full.
2. Claim 35 and new claims 48-55 are pending.
3. Applicant is notified that any outstanding rejections or objections that are not expressly maintained in this Office action have been withdrawn.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 35 and new claims 49-55 are rejected under 35 U.S.C. 112, first paragraph, as set forth previously, because the specification, while being enabling for methods of identifying a chemical that specifically binds to a polypeptide having an amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for methods encompassing polypeptides having less than 100% identity to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that the examiner has provided no reasons which would lead one to doubt that the specification describes how to make and use the claimed subject matter. This

Art Unit: 1646

argument has been fully considered but not deemed persuasive, Applicant is referred to the previous office action wherein a detailed analysis of art-recognized problems associated with constructing active amino acid sequence variants of proteins has been given.

Applicant argues that the claims recite a limited genus, e.g. 70% sequence identity with, or comprising 20 consecutive amino acids of, SEQ ID NO: 2; wherein the genus is further limited by the requirement that the polypeptide bind GABA. This argument has been fully considered but not deemed persuasive. The skilled artisan appreciates that the number of potential distinct polypeptides having 70% sequence identity with, or comprising 20 consecutive amino acids of, SEQ ID NO: 2 is astronomical, and for practical purposes, is essentially limitless. Of these, the specification merely offers the skilled artisan the invitation to randomly make and then to test each to try to find polypeptides that bind GABA. Such random trial and error experimentation is undue. The specification has failed to teach one of skill in the art which amino acid substitutions, deletions or insertions to make that will preserve the GABA binding function of the protein corresponding to SEQ ID NO: 2.

Applicant argues that the skilled artisan could readily use the polynucleotide information provided in the specification to find polynucleotides encoding the required polypeptides from other species, e.g. other insect species. This argument has been fully considered but not deemed persuasive. Again, these teachings are merely an invitation to the skilled artisan to begin an essentially random strategy of experimentation, wherein the artisan tries to find related polynucleotides that are encompassed by the claims from other species. However, specific and

Art Unit: 1646

not general guidance is required. The specification has not provided adequate guidance as to what species should contain polynucleotides that meet the limitations of the claims, nor what PCR primers, probes, etc. to use. Thus, this invitation to perform random trial and error experimentation is considered undue.

Applicant argues, essentially, that tremendous advances in the field have greatly simplified the process of making and testing the encompassed variants. This argument has been fully considered but not deemed persuasive. The examiner is aware of no such advances that would allow the skilled artisan to make and screen the claimed genus of variant neurotransmitter receptors without undue experimentation, and nor has Applicant provided such examples.

Applicant argues that the specification teaches how to use the encompassed polypeptides without knowledge of the precise function, e.g. to search for new insecticidal compounds. This argument has been fully considered but not deemed persuasive. It is unclear how one would use a polypeptide that is only 70% identical to a naturally occurring peptide in order to search for new insecticidal compounds; and it is unclear which part of the specification Applicant is now referring to.

Applicant again argues that no objective evidence has been presented to justify the assertion of lack of enablement. Applicant is again referred to the previous Office action wherein Bowie et al. was cited as evidence that the effect of amino acid substitution on function is unpredictable and wherein Alexander et al. was cited as evidence that the effect of amino acid substitution on antigenicity is also unpredictable. Thus, absent any additionally information as to

Art Unit: 1646

the particular amino acid substitutions that should be made, the skilled artisan appreciates from these teachings that it is essentially a trial and error processes to develop amino acid sequence variants of a protein having particular functions/activities or producing particular antigenic determinants. An invitation to begin such experimentation, as offered by the instant specification, is not a substitute for such experimentation, and to perform such experimentation is considered unduly burdensome.

Applicant's reliance on *Ex parte Mark* is misplaced. In that case, there were only a small number of mutants to be made and tested for any given protein - and the positions of the amino acid substitutions to be made was defined, i.e. mutations were to be made at the cysteine residues. The instant fact pattern is entirely different from that of *Mark*. The instant claims are direct to an essentially limitless and random assortment of mutations relative to the given protein. To make and test a number of such mutants, commensurate with that which is claimed, would be unduly burdensome.

Art Unit: 1646

***Conclusion***

6. Claim 48 is allowable.
7. Claims 35 and 49-55 are not allowable.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Art Unit: 1646

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



January 7, 2003

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER